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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/01/1999

MICHAEL J. WARING

CV0244

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07/07/2009

CONVATEC INC.

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EXAMINER

GHALI, ISIS A D

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

07/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/341,821	Applicant(s) WARING ET AL.	
	Examiner Isis A. Ghali	Art Unit 1611	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 June 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 19 June 2009. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: _____.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
 13. ☐ Other: _____.

/Isis A Ghali/
 Primary Examiner, Art Unit 1611

Continuation of 11. does NOT place the application in condition for allowance because:

Claims 5, 6, 8-10, 14, 15, 18-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of EP 0 666 081 ('081), US 3,788,521 ('521) and US 3,976,223 ('223).

It is submitted that the final action was made in response to applicant's rely filed 11/13/2008, and the date of 12/17/2008 was typographical error.

Applicant argues that '223 is cited to show an aerosol container containing a gel. However, the purpose of the package of '223 is to separately store a plurality of flowable substances in a single package from which such substances may be dispensed. According to '223, only the lower chamber of the outer container is pressurized with a gas through a self-sealing plug in the container bottom. Since only the lower chamber of the outer container of '223 is pressurized with a gas through a self-sealing plug, the container in '223 is not self-sealing as required in the rejected claims. Moreover, it is submitted that '223 does not address the avoidance of contamination during use. Rather, any avoidance of contamination appears to be with respect to storage.

In response to this argument, US '223 is relied upon for teaching gel can be delivered from a pressurized aerosol container. US '223 is interested in making gel in aerosol for spraying. US '223 solved problem of keeping reactive components that may interfere with one another prior to application apart until dispersion from the container. It necessarily follows from the teaching of EP '081 and US '223 that one would use single compartment vessel when there was no issue of reactivity or degradation of components of the composition. Additionally, the dispensing valve disclosed by US '223 is kept shut with a compression spring [30] that prevents the flowable materials present in the containers from entering into the exit passageway, col.3, lines 28-47. The exit ports are opened by depressing the compression spring to actuate the dispensing valve, col. 4, lines 35-40. Once actuated, the "the gas under pressure in pressure tight chamber B" forces the piston upward, pushing the flowable materials through the exit passageway and out through the dispensing valve, col.4, lines 38-45. As a result, "a uniform, metered amount of the flowable material" is discharged from the package, col.4, lines 46-58. US '223 indicates that "dispensing valve assembly" forms "a pressure tight closure when the valve is closed, col.3, lines 20-24. This structure described by US '223 can be characterized as "self-sealing" since the compression spring [30] in combination with the lower pressurized container keep the valve shut. US '223 states that the "relative metering" of the flowable material from the container "is constant throughout the life of the dispenser," indicating that it contains "multiple doses," as required by claim 1, col.4, line 66-col.5, line 2. Further, self sealing valve disclosed by US '223 reads on the present self-sealing in light of applicants' disclosure and figure 1 that set forth two meaning for self-sealing, and one of them is the valve in the bottom of the container used to fill the container with the pressurized gas.

Applicant argues that '521 does not teach delivering gel. The problem addressed by '521 concerns emptying the container and having a uniform product dispensed. Applicants' invention is concerned with packaging a gel so that the packaging can be used to dispense more than one dose without compromising the sterility of the remaining doses. Moreover, one of ordinary skill in the art at the time the invention was made did not put wound gels in barrier aerosol containers and would not look to the hair coloring/shaving cream art of '521.

In response to this argument, it is argued that US '521 was involved in the rejection for teaching aerosol container having single inner and single outer container separated by pressurized gas, because US '521 teaches that the discharged product from such as aerosol has a uniform density and maintained a predetermined physical characteristic all the life of the package. US '521 teaches the aerosol vessel disclosed by applicants. The prior art is used to all it teaches to one having ordinary skill in the art. Gel in an aerosol is taught by US '233 and gel wound dressing composition is taught by EP '081.

It is asserted in the Action that this is simply an argument against the references individually. However, contrary to that position, Applicants submit that they must provide comments on the cited art. Explaining the inapplicability of a piece of art does not, in and of itself, mean Applicants are arguing that piece by itself. Further, according to the Action, "US '223 is relied upon for teaching gel can be delivered from a pressurized aerosol container." Applicants have explained why the actual teaching of US '223 is inapplicable here. As noted above, the purpose of the package of '223 is to separately store a plurality of flowable substances in a single package from which such substances may be dispensed. To say that "[I]t necessarily (sic) follows from the teaching of EP '081 and US '223 that one would use (sic) single compartment vessel when there was no issue of reactivity or degradation of components of the composition" guts the whole teaching of US '223. While it may be "proper to take into account not only the specific teachings of the references but also the inferences which one skilled in the art would reasonably be expected to draw therefrom", one cannot gut the actual teachings of the references to combine them for some superficial notion. It cannot be casually argued that the rational to combine teachings "may be expressly or impliedly contained in the prior art" when the rational is neither. This is the situation here. Applicants' invention is concerned with packaging a gel so that the packaging can be used to dispense more than one dose without compromising the sterility of the remaining doses.

In response to this argument, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide wound dressing gel deliverable from a nozzle for treating cavities comprising natural gelling agent, hydrocolloid, alkylene glycol and water as disclosed by EP '081, and one having ordinary skill in the art knowing that wound dressing gels can be delivered from an aerosol package as disclosed by US '223 would have been motivated to replace the delivery means that have a nozzle with an aerosol package, and further use the aerosol package disclosed by US '521 having inner and outer container separated by pressurized gas, motivated by the teaching of US '521 that the discharged product from such as aerosol has a uniform density and maintained a predetermined physical characteristic all the life of the package, with reasonable expectation of having wound dressing gel delivered from an aerosol package having inner container and outer container separated by a pressurized gas and meanwhile the delivered gel will have a uniform density and maintain a predetermined physical characteristic all the

life of the package. It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." KSR Int '1 Co. v. Teleflex Inc., 127 S.Ct. 1727, 1740 (2007) (quoting Sakraida v. AG Pro, Inc., 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR INTERNATIONAL CO. v. TELEFLEXINC. ET AL. (2007). A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. In re Bozek, 163 USPQ 545 (CCPA 1969). In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims as a whole would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).